Planning for BioShield

Acquisition of Medical Countermeasures

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Operational concepts

- HHS will contract for vaccines and other countermeasures that are in late stages of development
  - Satisfactory Phase 1 or 2 trial data
  - Animal data demonstrating efficacy
  - No major obstacles to licensure
  - Large scale manufacturing capability
- Contracting will be for delivery of products
- Acquisition contracts may be concurrent with NIH R&D contracts

Operational Concepts

- NIH funding
  - Preclinical development
  - Pilot production
  - Phase 1 and early Phase 2 trials
  - Initial animal efficacy studies
  - Process development
- BioShield Funding
  - Manufacturing at scale
  - Phase 3 trials
  - Pivotal animal efficacy studies
  - BLA submission

Operational Concepts

- Products will be stockpiled initially in IND status
  - CDC will hold emergency use protocols
- Contracts will contain financial incentives to assure licensure as soon as feasible
- More than one manufacturer will be sought for major items
- U.S. based manufacturing is desirable

Release of BioShield Funds

- Approval of Requirement – Interagency coordination up to the Deputies Committee
- Findings by Secretaries of DHS and HHS
  - Determination of material threat
  - Suitability of countermeasure
  - No significant commercial market
  - Numbers of doses required and cost
- Approval by the President

Candidates for BioShield Purchase

- Anthrax vaccine - rPA
- Safer smallpox vaccine - attenuated vaccinia
- Anthrax immune products – monoclonal antibodies, transgenic immune globulins
- Botulinum vaccine and antitoxins
- Plague vaccine
- Hemorrhagic fever vaccines
  - Ebola, Marburg, RVF

Medical Countermeasures Acquisition Planning

Interagency Coordination

- Weapons of Mass Destruction Medical Countermeasure Subcommittee (WMDMCS)
  - Convened by OSTP and HSC
  - Co-chairs - HHS and DoD
  - Coordinates requirements and acquisition strategies across agencies
  - Coordinates R&D and addresses vulnerabilities and gaps in R&D
  - Provides options and recommendations for acquisition to the Department Secretaries

Leadership of WMDMCS Subgroups

- Requirements - CDC, DoD
- Acquisition Strategy - HHS, DHS
- R&D Gaps - NIH, USAMRMC
- Diagnostic methods – NIH, USAMRIID
- Drugs (antibiotics and antivirals) – HHS, DoD
- Radiation - HHS, DoD
- Animal diseases - USDA
- Industrial Relations - Commerce
- Special Immunizations - HHS

Requirements

- Requirements documents produced for:
  - Anthrax vaccine
  - Anthrax immune products
  - Safer smallpox vaccine
  - Botulinum antitoxins
  - Botulinum vaccine
  - Tularemia vaccine

rPA Anthrax vaccine

- Two NIH contractors, Avecia and VaxGen
- Different manufacturing methods for similar product
  - Avecia - *E. coli*
  - Vaxgen - *B. anthracis* (asporogenic)
- Phase 1 trials underway
- Preclinical animal data is promising
- Manufacturing at scale in mid 2004
- HHS Planning for first BioShield Contract

BioShield Contracting Risk

Early Product Development

Animal model development
Preclinical studies
Pilot production
IND, Phase 1 trials
Process development

Intermediate Product Development

Assay validation
Efficacy evaluation
Intermediate scale manufacturing (up to 5M)
Phase 2 trials

Highest

Lowest

“RISK”

BioShield Acquisition

Botulinum Antitoxins

- Bivalent Anti-AB Antitoxin – 15,000 doses in SNS
- Equine antitoxin from plasma – estimated 11,700 heptavalent, 10,200 pentavalent and 16,500 monovalent doses to be in stockpile by June 04
- New Equine Program – Contracts have been awarded for immunization of horses, target is 200,000 doses of heptavalent antitoxin.
- Anti-E Antitoxin – 1,000 doses have been vialed by Aventis and are awaiting purchase by SNS

Safer Smallpox Vaccine

- NIH funded R&D program for MVA progressing well
  - Two contractors
    - Bavarian Nordic
    - Acambis
  - Phase 1 and non-human primate studies
- VaxGen independently developing LC16m8
- Could be considered for BioShield contracting in mid-2004
- Requirements being debated